Remarks

Claims 1, 2, 4-10 and 13 are pending and directed generally to methods of treating or preventing gastritis and/or gastric ulceration in a subject by administering a therapeutically effective amount of an amylin or an amylin agonist, but not a calcitonin or a CGRP. All of the claims stand rejected over alleged prior art, as well as over alleged violations of 35 USC § 112. Reconsideration and withdrawal of these rejections is respectfully requested.

New dependent claims 14-16 and 19-24 have been added. Claims 14, 18, and 19 recite amylin and amylin agonist IC_{50} ranges (specification support, e.g., p. 36, line 24, p. 37 (Table 1), and p. 30 (Example 1)). Claims 15 and 16 recite treatment or prevention of ethanol- or NSAID-induced gastritis or gastric ulceration (specification support, e.g., p. 11, lines 23-25, and p 30, lines 3-5). Claims 20-24 are addressed to specific modes of peripheral administration (see, e.g., claim 6 as originally filed).

New independent claim 17 recites a method for treating or preventing an ethanol-induced gastritis or gastric ulceration in a subject using an amylin or amylin agonist. New claim 18 depends from claim 17 and recites an IC_{50} value of about 50 pM or less.

No new matter has been added.

I. REJECTION OF CLAIMS 1, 2, 5, 6, AND 13 UNDER 35 USC 102(a) AND/OR 35 USC 103(a) OVER WPIDS ABSTRACT NO. 98-019088 TO LIU ET AL.

The Examiner has maintained rejections over an abstract by Liu et al. which refers to a Chinese medicine and mentions the word "amylin" in connection with treating gastrosis. The Examiner equates "gastrosis" with gastritis and gastric ulcers without further comment or support. The Examiner equates "amylin" with the pancreatic hormone amylin referred to in Applicant's specification and claims. Plainly, the "amylin" referred to in Liu et al. is not the same as the pancreatic hormone amylin. In support of this unmistakable fact, Applicants submit the attached Exhibit 1 excerpt from an English-Chinese Medical Dictionary. The word "amylin" appears on page 82 and is understood to translate essentially to "a starch metabolite derived by the action of amylose," thus supporting Applicants' contentions. Consistent with this definition, the term "amylin" as used in the Liu abstract is manifestly relegated to a subsidiary role in the admixture. The active ingredients are listed first, while subsidiary "fillers" follow. The term "amylin" appears among the fillers, e.g., sugars and starches, and not among the active primary

ingredients. Plainly, this is not the pancreatic hormone known as amylin, which is neither a Chinese medicine, nor a filler.

Accordingly, Applicants respectfully submit that the rejection cannot stand and should be withdrawn.

II. REJECTION OF CLAIMS 1-2, 5-8, AND 13 UNDER 35 USC 102(b) OVER KOLTERMAN ET AL.

The Examiner has alleged that the Kolterman et al. publication inherently anticipates the claims.

To anticipate a claim, a prior art reference must disclose each and every limitation of the claimed invention, either explicitly or inherently. *Mehl/Biophile Intern. Corp. v. Migraum*, 192 F.3d 1362 (Fed. Cir. 1999), quoting *In re Schreiber*, 128 F.3d 1473 (Fed. Cir. 1997). However, it is well-settled that inherency may not be established by probabilities or possibilities; the mere fact that a certain thing may result from a given set of circumstances is not sufficient. *Mehl/Biophile*, 192 F.3d at 1365 (quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981). In other words, occasional methods and results consistent with the invention are not inherent. *Id.*

In *Mehl/Biophile*, the claims in issue were directed to methods of removing hair using a laser. The defendant asserted that an instruction manual that taught removing tattoos with a laser "inherently" anticipated the claim. The lower court, and the Federal Circuit on appeal, rejected this argument, stating that the claim step, "aligning laser over a hair follicle opening," was not inherent in the manual's disclosure, notwithstanding the "possibility" and "occasional result" of such an alignment in the prior art method.

Kolterman et al. describes modification of glucose metabolism, gastric motility, and emptying rates using amylin. The instant claims, by contrast, are directed to treating or preventing gastritis and gastric ulceration. Viewing the Examiner's assertion in the best possible light and although Applicants disagree, as enunciated in *Mehl/Biophile*, there is only the possibility of a result, and no certainty of result. This is because to *prevent* gastritis, one first needs a subject that is at risk for gastritis. Similarly, to *treat* gastritis, one first requires a patient that has gastritis. Further, owing to biochemical differences between individual subjects, some subjects will never be at risk for or contract gastritis, which makes administering amylin to such subjects unnecessary and futile in furtherance of the claim objective.

Accordingly, as in *Mehl/Biophile*, the limitations of the claims are not present at least for the reason that the subjects in Kolterman et al. were uncharacterized in any respect with regard to gastritis, thus only promoting the possibility, and not certainty, of satisfaction of the instant claim objectives. The rodents, dogs, and humans described in Kolterman were, at most, only ostensibly characterized with respect to diabetes, and not gastritis.

The cases relied upon by the Examiner are distinguishable. For example, the claims in *In re Best*, 195 USPQ 430 (CCPA 1977), were directed to zeolitic molecular sieve catalyst compositions useful in hydrocarbon conversion and to processes for producing them. The rejections in *Best* hinged on a rate of cooling limitation that the Board and CCPA found to represent a standard, normal rate, which was *certain,* and not merely *possible*. Applicants did not sufficiently rebut this contention.

In *Ex Parte Novitski*, 26 USPQ2d 1389 (BPAI 1993), the Board reversed a rejection based on alleged obviousness, but imposed a new rejection for anticipation by inherency. The Board reasoned that a certain prior art reference appeared to teach to a certainty, and not a mere possibility, a method of protecting a plant against nematodes using an anti-nematodal agent.

III. REJECTION OF CLAIMS 1, 2, AND 5-6 UNDER 35 USC 103(a) OVER THE COMBINATION OF EVANS, GRAY ET AL., MAGGI ET AL., AND GHECZY ET AL.

The Examiner has rejected claims 1, 2, and 5-6 over the combination of Evans, Gray et al., Maggi et al., and Gheczy et al.

It is well settled that before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Jones*, 21 USPQ2d 1941 (Fed. Cir. 1992) (citing *In re Fine*, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988)). There must be some objective suggestion in the art to do what Applicants have claimed. Further, the teaching or suggestion to combine must be "clear and particular," and not merely "[b]road conclusory statements regarding the teaching of multiple references." *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). An alleged reference "must also be read not in isolation, but for what it fairly teaches in combination with the prior art as a whole." *In re Merck & Co.*, 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). Not only must the whole of the prior art be considered, but so must the whole of an individual reference—especially when portions thereof argue against or teach

away from the claimed invention. *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992); *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1988)("Evidence that supports, rather than negates, patentability must be fairly considered"); *In re Chupp*, 2 U.S.P.Q.2d 1437 (Fed. Cir. 1987); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986). In general, a reference teaches away if it suggests that the line of development flowing from the disclosure of the alleged reference is unlikely to be productive of the result sought by applicants. *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994), citing *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966).

Evans reports that IV- and ICV-administered CGRP, and a homolog variant thereof at amino acid 35, allegedly lowered pentagastrin-induced gastric acid secretion in rats and dogs. Gray et al. report a similar alleged effect for rats administered intragastral acid and NSAIDs. Maggi et al. is essentially the same as Gray et al., with the additional caveat that ETOH-induced gastric lesions and ulcers in particular were reported not to appear to be treatable or preventable using CGRP.[1] None of these studies mention or suggest using amylin.

Fundamentally, CGRP is not amylin, and the claims specifically exclude CGRP. Because the claim term, "amylin or an amylin agonist, wherein said amylin agonist is not a calcitonin or a CGRP," is not taught or suggested by any of Evans, Gray, or Maggi, alone or combined, this element remains unmet.

The Ghezy patent does not overcome the absence of this element. Ghezy merely teaches the use of NSAID analgesics in combination with phospholipids to prevent or minimize side effects, e.g., gastrointestinal bleeding and ulcers. Ghezy does not mention or suggest the specific claim limitation, "amylin or an amylin agonist, wherein said amylin agonist is not a calcitonin or a CGRP."

Last, the Examiner's own art, Guidobono et al. (1997), discussed *infra*, teaches away from peripheral treatments as now claimed: "Amylin given intracerebroventricularly... demonstrated a dose-dependent cytoprotective effect...[,whereas] amylin, given [peripherally, e.g.,] subcutaneously[,] at doses effective in inhibiting acid gastric secretion..., did not." Id., abstract, ¶2 (emphasis added).

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[1] This further supports the independent patentability of new claims 17 and 18, which do not specifically exclude calcitonins and CGRPs as agonists.

Accordingly, Applicants respectfully submit that the rejections over the combination of Evans, Gray, Maggi, and Gheczy cannot stand and should be withdrawn.

IV. REJECTION OF CLAIMS 1-2 AND 5-12 UNDER 35 USC 103(a) OVER THE COMBINATION OF EVANS ET AL., GRAY ET AL., MAGGI ET AL., AND BATES ET AL., IN VIEW OF AN ALLEGED SPECIFICATION ADMISSION ON PAGE 6, KOLTERMAN ET AL., AND/OR LIU ET AL.

This rejection is similar to that described in III., above, as concerns Evans et al., Gray et al., and Maggi et al. The remaining citations combined do not complete the rejection.

Bates et al. report on experiments said to evaluate the effect of salmon calcitonin on NSAID-induced gastric ulceration in rats and mice. Salmon calcitonin, like CGRP, is not amylin, and is excluded by the clear wording of the claims. Bates does not teach or suggest the use of amylin or other amylin agonists, as claimed.

Further, and significantly, Bates et al. state that the results using salmon calcitonin are very different as between rats and mice. Rats exhibit an effect while mice do not, at least when the calcitonin is administered intragastrally: "Thus it is possible to conclude that indomethacin-induced gastric ulceration in the rat, in contrast to the mouse, is sensitive to the antiulcerogenic actions of intragastrally administered calcitonin." Bates, pp. 483 P, column 2, top (emphasis added). The Examiner, ignoring the mice results, focuses selectively on the rat results:

> Accordingly it would have been obvious at the time of applicant's invention to utilize an amylin agonist (e.g., calcitonin and/or CGRP) alone to alleviate stomach inflammation (e.g., gastritis, ulcers, etc.) or concomitantly (e.g. in combined pharmaceuticals or in separate administrations) with NSAIDs in order to alleviate the undesirable side effects of NSAIDS (e.g., stomach inflammation and/or ulcers), with a reasonable expectation of success.

Office Action, July 12, 2000, Paper 14, pg. 10, ¶ 3.

This unfounded generalization by the Examiner is contrary to established law that the whole of a reference be considered, and not select, self-serving portions—especially when other portions argue against or teach away from the claimed invention. *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1988). The Examiner's position further is contrary to *In re Dembiczak*, which forbids "[b]road conclusory statements regarding the teaching of multiple references." 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

Nor does the alleged admission on page 6 of the specification support the rejection. The statement alleged to be an admission concerns only the ability of amylin and amylin agonists to inhibit gastric emptying in rats, dogs, and humans, i.e., to slow the emptying of the contents of the stomach following a meal. The Examiner does not clearly and particularly point out how this statement can be used in conjunction with the other documents to render the claimed invention obvious.

Furthermore, if as the Examiner suggests, gastroprotective or ameliorative functions equate with reduced gastric acid, one of skill would anticipate that slowed gastric emptying might induce and/or aggravate gastritis or ulceration by allowing localized gastric acid build-up to occur. However, Guidobono et al. (1997), suggests otherwise—that peripheral administration has no effect on gastroprotection: "Amylin given intracerebroventricularly...demonstrated a dose-dependent cytoprotective effect...[,whereas] amylin, given subcutaneously at doses effective in inhibiting acid gastric secretion..., did not." Id., abstract, ¶2 (emphasis added).

For reasons stated previously, the remaining documents—Liu et al, Kolterman et al., Evans, Gray et al., and Maggi et al.—all fail to complete the rejection. Liu et al.'s "amylin" is completely different from and has nothing whatsoever to do with Applicants' amylin peptide, Kolterman et al. does not teach or suggest treating or preventing gastritis or gastric ulceration, and Evans, Gray, and Maggi all relate to various experiments with CGRP or calcitonin, which molecules are expressly excluded from the claims.

Thus, there is nothing obvious within the meaning of 35 U.S.C. § 103 about the instant claims in light of the cited documents, and Applicants respectfully ask that the rejection be reconsidered and withdrawn.

V. REJECTION OF CLAIMS 1-2, 4-10 AND 13 UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

The Examiner alleges that the claims, with respect to exclusion of CGRP as an agonist, are not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully request that this rejection be reconsidered and withdrawn.

There is adequate written description, even though literal specification support is not required. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (BPAI 1993). All that is necessary is that one of ordinary skill in the art would have recognized at the time of filing that the inventors had

possession of the claimed invention. *Id.* And while § 2173.05(j) of the MPEP notes that a subgenus is not necessarily described by a genus encompassing it, the MPEP, citing *In re Wilder*, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984), also states that each case must be decided on its own facts. *Id.* Further, where a disclosure already recites the particular species within a genus that is later sought to be excluded in the claims, this satisfies the written description requirement. *In re Johnson*, 194 USPQ 187 (CCPA 1977). In *Johnson*, the Court of Customs and Patent Appeals held:

> It is for the inventor to decide what bounds of protection he will seek. In re Saunders, 58 CCPA 1316, 1327, 444 F.2d 599, 607, 170 USPQ 213, 220 (1971). To deny appellants...would, as this court said in Saunders: 'let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed.'
>
> * * *
>
> The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of §112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute.

Id. at 196; *accord In re Driscoll*, 195 USPQ 434 (CCPA 1977).

The instant case is consonant. Here, two species (CGRP and calcitonin) are excluded from the claims. Both are disclosed in the specification as filed, as are their functional differences with amylin. *See, e.g.*, specification, p. 3, lines 17-25; p. 4, lines 20 et seq., p. 7, lines 14, bridging p. 8, line 5. Nothing more is required under the law where, as here, the individual species sought to be excluded were disclosed in the application as originally filed.

The case cited by the Examiner, *Ex parte Grasselli*, 231 USPQ 393 (BPAI 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir.1984), is distinguishable. There the applicant amended his claims to a catalytic process in order to avoid prior art by adding negative limitations ("oxidation catalyst in the absence of sulfur and halogen" and "catalyst being free of uranium and the combination of vanadium and phosphorus"). However, the elements sought to be excluded were held not to be sufficiently described in the specification.

Accordingly, Applicants respectfully submit that the rejection for alleged lack of written description is unsound under the law, and should be reconsidered and withdrawn.

VI. REJECTION OF CLAIMS 1-2, 4-6, 9-10, AND 13 UNDER 35 USC 112, SECOND PARAGRAPH

The Examiner further alleges that Applicants' claims 1, 2, 4-6, 9-10, and 13 are indefinite as regard "a CGRP." The Examiner makes this rejection presumably based on Evans' disclosure of a CGRP homolog containing a variation at amino acid position 35. *See* discussion, pg. 7, *supra*.

A claim need only reasonably apprise those of skill in the art of its scope. *See, e.g., Andrew Corp. v. Gabriel Electronics, Inc.*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988), *cert. denied*, 488 US 927 (1988) (approving of the use of claim terms such as "close" and "substantially").

Here, the claims do that. One of ordinary skill in this art knows that a polypeptide such as CGRP having a single amino acid variation at amino acid position 35 still constitutes substantially CGRP.

Accordingly, the claims are definite under the law, and Applicants respectfully ask that this ground of rejection be withdrawn.

VII. REJECTION OF CLAIMS 1, 2, 4-6, 9-10 AND 13 UNDER 35 USC 102(a) OR 35 USC 103(a) OVER GUIDOBONO ET AL. (1997)

Contrary to the Examiner's assertions, Guidobono et al. (1997) supports patentability of the claims. The claims as amended recite peripheral administration. Guidobono et al. only teach ICV administration into the brain, and not peripheral administration. Guidobono et al. therefore lack an element of the claim and in effect teach away from the invention: "Amylin given intracerebroventricularly [ICV]...demonstrated a dose-dependent cytoprotective effect...[,whereas] amylin, given subcutaneously at doses effective in inhibiting acid gastric secretion..., did not." Id., abstract, ¶2 (emphasis added).

Moreover, Guidobono et al. (1997) further illustrate the differences between amylin, CGRP, and calcitonin, thus justifying the specific claim exclusions.

Accordingly, Applicants submit that this specific rejection is unfounded under the law, and should be reconsidered and withdrawn.

VIII. REJECTION OF CLAIMS 1, 2, 5, 6, AND 13 UNDER 35 USC 103(a) OVER GUIDOBONO ET AL. (1994)

In addition to rejections made over the 1997 article by Guidobono et al., the Examiner has also rejected claims 1, 2, 5, 6, and 13 for alleged obviousness over Guidobono et al. (1994). The Examiner asserts:

> Guidobono et al. (Peptides) teaches that amylin administered to rat peripherally (subcut) and intracerebroventricularly resulted in the inhibition of acid gastric secretion, and thus is gastroprotective.
>
> Accordingly, the Guidobono et al. reference would render obvious the use of amylin to prevent/treat gastric inflammation (e.g., ulcers) which result from acid gastric secretion in rats and in humans to which the rat model is extrapolatable. The determination of additional means of administration protocols is well within the skill of the art and prima facie obvious.

Office Action, July 12, 2000, Paper 14, pg. 17, ¶ 13 (emphasis added). There are at least two errors in this assertion. First, the Examiner assumes that a reduction of gastric acid, alone, is gastroprotective. However, as demonstrated previously, the 1997 Guidobono article absolutely refutes this:

> Amylin injected s.c., at doses previously shown to be effective in reducing gastric acid secretion by 65%, was not able to protect from gastric ulcers induced by Indo or by EtOH. These data thus emphasize that gastric protection by amylin involves mechanisms other than inhibition or neutralization of gastric acid secretion, in contrast with the classical antisecretory drugs...

Guidobono Br. J. Pharmacology, (1997) 120, 584, col. 1, bottom (emphasis added).

Under the law of obviousness, an alleged reference "must be read not in isolation, but for what it fairly teaches in combination with the prior art as a whole." *In re Merck & Co.*, 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). Not only must the whole of the prior art be considered, but so must the whole of an individual reference—especially when portions thereof argue against or teach away from the claimed invention. *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992); *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1988)("Evidence that supports, rather than negates, patentability must be fairly considered"). In general, a reference teaches away if it suggests that the line of development flowing from the disclosure of the alleged reference is unlikely to be productive of the result

sought by applicants. *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994), citing *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966).

As demonstrated above, the Examiner has failed not only to consider the art as a whole, but also to consider certain sections within the individual art citations of record, namely, Guidobono et al. (1997), that support patentability. Accordingly, Applicants respectfully submit that the rejection is improper on this ground alone, and request that it be withdrawn.

Also inappropriate is the Examiner's extrapolation of rat results to humans. This is inconsistent with the teachings of the Examiner's other cited article, Bates et al., Br. J. Of Pharmacology Vol. 67(3) (1979), pp. 483P-484P. *See* discussion, § IV., *supra.* Bates et al. noted different results as between rats and mice. *See* p. 483P, column 1. Because there is a greater difference phylogenetically (and thus physiologically and biochemically) between humans and rats as opposed to rats versus mice, one of ordinary skill in the art viewing the documents cited by the Examiner would not adopt the Examiner's conclusion. Such conclusion is clearly premature in light of the Examiner's own art citations and demonstrates the lack of a prima facie case.

Accordingly, Applicants submit that the rejection is inappropriate and respectfully ask that it be reconsidered and withdrawn.

IX. REJECTION OF CLAIMS 1, 2, 4-10 AND 13 UNDER 35 USC 103(a) OVER YOUNG IN VIEW OF GHYCZY ET AL., GUIDOBONO ET AL. (1997) AND/OR GUIDOBONO ET AL. (1994)

The Examiner has rejected claims 1,2, 4-10 and 13 as allegedly obvious over U.S. Patent 5,677,279, issued to Young and assigned to Amylin Pharmaceuticals, Inc., in view of various articles already discussed.

Title 35 of United States Code, § 103(c), provides:

> Subject matter developed by another person, which qualifies as prior art only under subsections(e), (f), and (g) of subsection 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Notwithstanding the merits of this assertion, 35 U.S.C. § 103(c) applies to the instant case in that the patented subject matter and the claimed invention were, at the time the invention was made,

owned by Amylin Pharmaceuticals, Inc. Therefore, there can be no § 103 rejection based on this patent. Moreover, and for reasons stated above, the combined teachings of the remaining documents do not suffice to make a prima facie case of obviousness.

Accordingly, Applicants submit that the rejection is inappropriate and respectfully ask that it be reconsidered and withdrawn.

X. CONCLUSION

For all of the foregoing reasons, Applicants respectfully submit that the rejections of record in the previous case are now overcome and a early notice of allowance to that effect is requested.

If the Examiner has any questions, or needs clarification of any matter, he is invited to contact the undersigned at (858) 720-2926.

Respectfully submitted,

Brobeck, Phleger & Harrison LLP

Dated: 3/12/01

By: _____
Edward O. Kreusser
Reg. No. 38,523

Brobeck, Phleger & Harrison LLP
12390 El Camino Real
San Diego, CA 92130
(858) 270-2500

Version with Markings to Show Changes Made

1. (Twice Amended) A method for treating or preventing gastritis in a subject, comprising peripherally administering to said subject a therapeutically effective amount of an amylin or an amylin agonist, wherein said amylin agonist is not a calcitonin or a CGRP.

2. (Twice Amended) A method for treating or preventing gastric ulceration in a subject, comprising peripherally administering to said subject a therapeutically effective amount of an amylin or an amylin agonist, wherein said amylin is not a calcitonin or a CGRP.

14. (New) The method of claim 1 or 2 wherein said IC_{50} of said amylin or amylin agonist is about 50 pM or less.

15. (New) The method of claim 1 or 2 wherein said gastritis or gastric ulceration is induced by a member selected from the group consisting of ethanol and NSAIDs.

16. (New) The method of claim 15 wherein said member is ethanol.

17. (New) A method for treating or preventing an ethanol-induced gastritis or gastric ulceration in a subject, comprising administering to said subject a therapeutically effective amount of an amylin or an amylin agonist.

18. (New) The method of claim 17 wherein said amylin or amylin agonist has an IC_{50} of about 50 pM or less.

19. (New) The method of claim 14 wherein said amylin or amylin agonist has an IC_{50} of about 30 pM or less.

20. (New) The method according to claim 6 wherein said route is nasal.

21. (New) The method according to claim 6 wherein said route is oral.

22. (New) The method according to claim 6 wherein said route is pulmonary.

23. (New) The method according to claim 6 wherein said route is transdermal.

24. (New) The method according to claim 6 wherein said route is buccal.